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Alexandria, VA 22313-1450

On

By

*June 22, 2004*  
*Michelle Nicely*  
Michelle Nicely

61 3739 IFW

PATENT

Attorney Docket No.: C-8-2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Paul O. Davison, et al.

Application No.: 09/735,426

Filed: April 29, 2000

For: ELECTROSURGICAL SYSTEMS  
AND METHODS FOR RECANALIZATION  
OF OCCLUDED BODY LUMENS

Commissioner for Patents  
Alexandria, VA 22313-1450

Examiner: Lee S. Cohen

Art Unit: 3739

**INFORMATION DISCLOSURE  
STATEMENT UNDER  
37 CFR §1.97 and §1.98**

Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. A copy of each is enclosed.

It is respectfully requested that the cited information be considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue there from.

This IDS is being filed after the filing of an RCE. Applicants believe that no fee is necessary. Should a fee be deemed necessary for submission of this IDS, the Commissioner is authorized to charge the required fee to Deposit Account No. 50-0359.

Respectfully submitted,

*Richard R. Batt*  
Richard R. Batt  
Reg. No. 43,485

*June 22, 2004*  
Date

ArthroCare Corporation  
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(408) 736-0224

FORM PTO-1449 (Modified)

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE

STATEMENT

(Use several sheets if necessary)

Attorney Docket No.

C-8-2

Application No.:

09/735,426

Applicant: Paul O. Davison, et al.

Filing Date:

April 29, 2000

Group: 3739

Reference Designation

U.S. PATENT DOCUMENTS

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date

## FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
___ AN	57-57802	04/05/82	JP	A61B	1/00	
___ AH	97/48345	12/24/97	WIPO	A61B	17/39	
___ AI	98/27880	07/02/98	WIPO	A61B	17/39	
___ AB	92/21278	12/10/92	WIPO	A61B	5/04	
___ AC	94/08654	04/28/94	WIPO	A61M	37/00	
___ AD	97/00647	01/09/97	WIPO	A61B	17/39	
___ AE	97/00646	01/09/97	WIPO	A61B	17/39	
___ AJ	2 327 350	01/27/99	UK	A61B	17/39	
___ AK	2 327 351	01/27/99	UK	A61B	17/39	
___ AL	2 327 352	01/27/99	UK	A61B	17/39	
___ AA	0 694 290	11/15/00	Europe	A61B	18/04	
___ AF	0 703 461	03/27/96	Europe	G01R	27/02	
___ AG	0 754 437	01/22/97	Europe	A61B	17/39	
___ AM	3930451	03/21/91	Germany	A61B	17/39	

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

___ AO	Pearce, John A. (1986) <i>Electrosurgery</i> , pgs. 17, 69-75, 87, John Wiley & Sons, New York.
___ AP	J.W. Ramsey et al. <i>Urological Research</i> Vol. 13, pp. 99-102 (1985).
___ AQ	V.E. Elsasser et al. <i>Acta Medico Technica</i> Vol. 24, No. 4, pp. 129-134 (1976).
___ AR	P.C. Nardella (1989) <i>SPIE</i> 1068:42-49 Radio Frequency Energy and Impedance Feedback
___ AS	R. Tucker et al., Abstract P14-11, p. 248, "A Bipolar Electrosurgical Turp Loop"
___ AT	R. Tucker et al. <i>J. of Urology</i> Vol. 141, pp. 662-665, (1989).
___ AU	R. Tucker et al. <i>Urological Research</i> Vol. 18, pp. 291-294 (1990).
___ AV	Kramolowsky et al. <i>J. of Urology</i> Vol. 143, pp. 275-277 (1990).

EXAMINER

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FORM PTO-1449 (Modified)  LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Attorney Docket No.  <div style="text-align: center; font-weight: bold;">C-8-2</div>		Application No.:  <div style="text-align: center; font-weight: bold;">09/735,426</div>	
			Applicant: <b>Paul O. Davison, et al.</b>			
			Filing Date: <b>April 29, 2000</b>		Group: 3739	
Office Designation			U.S. PATENT DOCUMENTS			
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
___ BK	57-117843	07/22/82	JP	A61B	17/39	
___ BL	99/51158	10/14/99	WIPO	A61B	17/39	
___ BM	99/51155	10/14/99	WIPO	A61B	17/36	
___ BF	97/48346	12/24/97	WIPO	A61B	17/39	
___ AW	95/34259	12/21/95	WIPO	A61F	5/48	
___ BN	98/27879	07/02/98	WIPO	A61B	17/36	
___ BE	97/24994	07/17/97	WIPO	A61B	17/39	
___ BD	97/24993	07/17/97	WIPO	A61B	17/39	
___ BO	97/24074	07/10/97	WIPO	A61B	17/39	
___ BC	97/24073	07/10/97	WIPO	A61B	17/39	
___ AX	93/13816	07/22/93	WIPO	A61B	17/36	
___ AY	90/07303	07/12/90	WIPO	A61B	17/39	
___ BG	98/07468	02/26/98	WIPO	A61N	1/40	
___ AZ	94/04220	03/03/94	WIPO	yes	A61N	
___ BB	96/00042	01/04/96	WIPO	A61B	17/39	
___ BH	2 308 979	07/16/97	GB	A61B	17/36	
___ BI	2 308 980	07/16/97	GB	A61B	17/36	
___ BJ	2 308 981	07/16/97	GB	A61B	17/36	
___ BA	0 740 926 A2	11/06/96	EP	A61B	17/39	
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
___ BP	Kramolowsky et al. <i>J. of Urology</i> Vol. 146, pp. 669-674 (1991).					
___ BQ	Slager et al. <i>Z. Kardiol.</i> 76:Suppl. 6, 67-71 (1987).					
___ BR	Slager et al. <i>JACC</i> 5(6):1382-6 (1985).					
___ BS	Olsen MD, Bipolar Laparoscopic Cholecstectomy Lecture (marked confidential), 10/07/91					
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FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
___ BU1	93/20747	10/28/93	WIPO	A61B	5/00	
___ BT	90/03152	04/05/90	WIPO	A61B	17/39	
___ BU	2313949	01/07/77	France	A61N	3/02	

  

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)	
___ BV	Codman & Shurtleff, Inc. "The Malis Bipolar Electrosurgical System CMC-III Instruction Manual" 7/1991
___ BW	Valley Forge's New Products, CLINICA, 475, 5, 11/6/91
___ BX	Valley Forge Scientific Corp., "Summary of Safety and Effective Information from 510K," 1991
___ BY	Codman & Shurtleff, Inc. "The Malis Bipolar Coagulating and Bipolar Cutting System CMC-II" brochure, early 1991
___ BZ	L. Malis, "The Value of Irrigation During Bipolar Coagulation" See ARTC 21602, early 4/9/93
___ CA	L. Malis, "Excerpted from a seminar by Leonard I. Malis, M.D. at the 1995 American Association of Neurological Surgeons Meeting," 1995
___ CB	L. Malis, "Electrosurgery, Technical Note," J. Neurosurg., Vol. 85, 970-975, 11/96
___ CC	Ian E. Shuman, "Bipolar Versus Monopolar Electrosurgery: Clinical Applications," Dentistry Today, Vol. 20, No. 12, 12/01
___ CD	Protell et al., "Computer-Assisted Electrocoagulation: Bipolar v. Monopolar in the Treatment of Experimental Canine Gastric Ulcer Bleeding," Gastroenterology Vol. 80, No. 3, pp. 451-455
___ CE	Cook and Webster, "Therapeutic Medical Devices: Application and Design," 1982
___ CF	Valleylab SSE2L Instruction Manual, 1/6/83
___ CG	Robert D. Tucker et al., "Demodulated Low Frequency Currents from Electrosurgical Procedures," Surgery, Gynecology and Obstetrics, 159:39-43, 1984
___ CH	Lu, et al., "Electrical Thermal Angioplasty: Catheter Design Features, In Vitro Tissue Ablation Studies and In Vitro Experimental Findings," Am J. Cardiol Vol. 60, pp. 1117-1122

  

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<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>						
___ CH	Selikowitz & LaCourse, "Electric Current and Voltage Recordings on the Myocardium During Electrosurgical Procedures in Canines," <i>Surgery, Gynecology &amp; Obstetrics</i> , Vol. 164, 219-224, March 1987					
___ CI	J. O'Malley, Schaum's Outline of Theory and Problems of Basic Circuit Analysis, McGraw-Hill, 2 <sup>nd</sup> Ed., 1992, pp. 3-5					
___ CJ	Arnaud Wattiez et al., "Electrosurgery in Operative Endoscopy," <i>Electrosurgical Effects</i> , Blackwell Science, pp. 85-93, 1995					
___ CK	Leslie A. Geddes, "Medical Device Accidents: With Illustrative Cases" CRC Press, 1998					
___ CL	Wyeth, "Electrosurgical Unit" pp. 1181-1202					
___ CM	C.P. Swain, et al., <i>Gut</i> Vol. 25, pp. 1424-1431 (1984)					
___ CN	Piercey et al., <i>Gastroenterology</i> Vol. 74(3), pp. 527-534 (1978)					
___ CO	A.K. Dobbie <i>Bio-Medical Engineering</i> Vol. 4, pp. 206-216 (1969)					
___ CP	B. Lee et al. <i>JACC</i> Vol. 13(5), pp. 1167-1175 (1989)					
___ CQ	K. Barry et al. <i>American Heart Journal</i> Vol. 117, pp. 332-341 (1982)					
___ CR	W. Honig <i>IEEE</i> pp. 58-65 (1975)					
___ CS	Jacob Kline, <i>Handbook of Biomedical Engineering</i> , Academic Press Inc., N.Y., pp. 98-113, 1988					
___ CT	M.B. Dennis et al. "Evolution of Electrofulguration in Control of Bleeding of Experimental Gastric Ulcers," <i>Digestive Diseases and Sciences</i> , Vol. 24, No. 11, 845-848					
___ CU	Letter from Department of Health to Jerry Malis dated April 15, 1985					
___ CV	Letter from Jerry Malis to FDA dated July 25, 1985					
___ CW	Letter from Department of Health to Jerry Malis dated 04/22/91					
___ CX	Leonard Malis, "Instrumentation for Microvascular Neurosurgery" <i>Cerebrovascular Surgery</i> , Vol 1, 245-260, 1985.					
___ CY	Valleylab, Inc. "Valleylab Part Number 945 100 102 A" Surgistat Service Manual, 7/88					
___ Cz	Leonard I. Malis, "New Trends in Microsurgery and Applied Technology," <i>Advanced Technology in Neurosurgery</i> , 1-16, 1988					
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## FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (yes/no)
____ DA	29609350	5/24/96	DE			Yes
____ DB	98/38925	9/11/98	WO			
____ DC	98/39038	9/11/98	WO			
____ DD	19537084	4/10/97	DE			Yes
____ DE	0553576	4/17/96	EP			
____ DF	0515867	7/7/99	EP			
____ DG	29619029	4/10/97	DE			Yes
____ DH	94/14383	7/7/94	WO			
____ DI	96/39965	12/19/96	WO			
____ DJ	96/39963	12/19/96	WO			
____ DK	96/39962	12/19/96	WO			
____ DL	96/35469	11/14/96	WO			
____ DM	98/30144	7/16/98	WO			
____ DN	98/27877	7/2/98	WO			
____ DO	98/23324	6/4/98	WO			
____ DP	98/19614	5/14/98	WO			
____ DQ	98/17186	4/30/98	WO			
____ DR	98/17185	4/30/98	WO			
____ DS	97/44071	11/27/97	WO			
____ DT	97/34540	9/25/97	WO			
____ DU	97/25101	7/17/97	WO			

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

____ DV	Regional myocardial blood flow and cardiac mechanics in dog hearts with CO <sub>2</sub> laser-induced intramyocardial revascularization, Basic Research in Cardiology 85:179-197(1990) R. Hardy, F. James, R Millard and S. Kaplan
____ DW	Transventricular Revascularization by Laser, Lasers in Surgery and Medicine 2:187-198(1982) M. Mirhoseini MD, Muckerheide, and Cayton RN
____ DX	Transmyocardial Laser Revascularization: A Review; J. Of Clinical Laser Medicine & Surgery V. 11, No. 1 1993 pp 15-19; M. Mirhoseini, MD, S. Shelgikar MD, M Cayton RN,

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Examiner: Lee S. Cohen

Art Unit: 3739

**COMMUNICATION**

Sir:

The following information is being brought to the Examiner's attention.

I. LITIGATION ACTIVITY

A. *Ethicon* litigation

Applicant brings the following information and list of materials to the attention of the Examiner. On February 13, 1998, ArthroCare Corporation filed a lawsuit in the United States District Court for the Northern District of California against defendants Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc., alleging infringement of U.S. Patent Nos. 5,697,909, 5,697,536, 5,697,281, and 5,697,882. The case was assigned Case No. C98-00609 WHO (the "*Ethicon* litigation"). The *Ethicon* litigation terminated in June 1999, with the defendants taking a license from ArthroCare under the patents-in-suit. The defendants paid ArthroCare a license fee and have paid ongoing royalties on sales in the United States of certain arthroscopy and gynecology products covered by these patents.

After the *Ethicon* litigation terminated, Applicant was apprised by a third party of section 2001.06(c) of the Manual of Patent Examining Procedure ("MPEP") with respect to the

prosecution of applications for patents other than those at issue in the *Ethicon* litigation and that were pending before the *Ethicon* litigation was commenced, namely, U.S. Application Nos. 08/807,111 (now U.S. Patent No. 5,891,095), 08/766,382 (now U.S. Patent No. 5,888,198), and 08/760,768 (now U.S. Patent No. 5,766,153).

Although not required to do so, Applicant did bring the *Ethicon* litigation to the attention of Examiner Mendez during the prosecution of at least U.S. Application Nos. 08/807,111 (now U.S. Patent No. 5,891,095), 08/766,382 (now U.S. Patent No. 5,888,198), and 08/795,686 (now U.S. Patent No. 5,871,469), during a telephone conference relating to those applications. Applicant also submitted the prior art that was principally relied on by the defendants in the *Ethicon* litigation to Examiner Mendez during the prosecution of U.S. Application Nos. 08/807,111 (now U.S. Patent No. 5,891,095), 08/766,382 (now U.S. Patent No. 5,888,198), and 08/795,686 (now U.S. Patent No. 5,871,469). Indeed, Applicant withdrew one of those pending applications, namely, U.S. Application No. 08/807,111 (now U.S. Patent No. 5,891,095), from allowance to provide Examiner Mendez with the opportunity to consider those references.

In addition, Applicant provides the following list of materials from the *Ethicon* litigation that reflect the defendants' and ArthroCare's primary arguments relating to issues of validity and enforceability:

1. ArthroCare's Complaint For Patent Infringement Of U.S. Patent Nos. 5,697,909; 5,697,281; 5,697,882; And 5,697,536 filed February 13, 1998;
2. Plaintiff ArthroCare's Motion For Preliminary Injunction Against Defendant Ethicon And Mitek, filed March 10, 1998.
3. Answer And Counterclaim Of Defendants Ethicon, Inc., Mitek Surgical Products, Inc., And Gynecare, Inc., filed April 6, 1998;
4. Plaintiff ArthroCare's Motion To Strike Affirmative Defenses And To Strike Defendants' Counterclaim In Part Or, In The Alternative, For a More Definite Statement, filed April 17, 1998;
5. Defendants' Opposition To ArthroCare's Motion To Strike Affirmative Defenses And To Strike Defendants' Counterclaim In Part Or, In The Alternative For A More Definite Statement And Points And Authorities In Support Of Conditional Motion To File An Amended Answer And Counterclaim, filed May 7, 1998;



6. ArthroCare's Reply In Support of Motion To Strike Affirmative Defenses And To Strike Defendants' Counterclaim In Part Or, In The Alternative, For A More Definite Statement, filed May 14, 1998;
7. Memorandum Decision And Order Regarding ArthroCare's Motion To Strike And Defendants' Motion For Leave To File An Amended Answer And Counterclaim, issued June 5, 1998;
8. Amended Answer And Counterclaim of Defendants Ethicon, Inc., Mitek Surgical Products, Inc., And Gynecare, Inc., filed June 22, 1998;
9. ArthroCare's Reply to Defendants' Amended Counterclaim, filed July 6, 1998;
10. ArthroCare's Initial Disclosure Of Asserted Claims Pursuant To Local Rule 16-7, served March 30, 1998;
11. Defendants' Initial Disclosure of Prior Art Pursuant To Local Rule 16-7, served May 26, 1998;
12. Plaintiff ArthroCare's Corporation's Opening Claim Construction Brief, filed May 11, 1998;
13. Ethicon, Inc.'s Claim Construction Brief, filed May 22, 1998;
14. Joint Claim Construction Statement Pursuant To Civil Local Rule 16-11(b)(1) For Claim Construction Hearing, filed May 29, 1998;
15. Plaintiff ArthroCare's Corporation's Reply To Defendants' Claim Construction Brief, filed May 29, 1998;
16. Memorandum Decision And Order Regarding Claim Construction, issued July 6, 1998;
17. Defendants' Petition For Permission To Appeal Pursuant To 28 U.S.C. §1292(b) filed with the U.S. Court of Appeals for the Federal Circuit on July 16, 1998;
18. Plaintiff's Answer To Defendants' Petition For Permission To Appeal Pursuant To 28 U.S.C. §1292(b), filed July 23, 1998;
19. Federal Circuit's Order On Petition For Permission To Appeal, issued August 20, 1998;
20. Summary Of Defendant Ethicon's Opposition To Plaintiff ArthroCare's Motion For Preliminary Injunction, filed July 23, 1998;
21. Ethicon's Opposition To Plaintiff ArthroCare's Motion For Preliminary Injunction, filed July 23, 1998;
22. Declaration Of John R. LaCourse In Opposition To ArthroCare's Motion For Preliminary Injunction, filed July 23, 1998;
23. Declaration Of Robert D. Tucker Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed July 23, 1998;

24. Declaration Of Robert A. Armitage, Esq., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction , filed July 23, 1998;
25. Supplemental Declaration Of Robert A. Armitage, Esq., In Support Of Ethicon's Opposition To Plaintiff ArthroCare's Motion For Preliminary Injunction, filed August 4, 1998;
26. ArthroCare's Reply Memorandum In Support Of Motion For Preliminary Injunction, filed August 6, 1998;
27. Declaration Of James Doss In Support Of ArthroCare's Motion For Preliminary Injunction, filed August 6, 1998;
28. Reply Declaration Of Philip E. Eggers In Support Of ArthroCare's Motion For Preliminary Injunction, filed August 6, 1998;
29. Reply Declaration Of John T. Raffle In Support Of ArthroCare's Motion For Preliminary Injunction, filed August 6, 1998;
30. Ethicon's Supplemental Opposition To Plaintiff ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998.
31. Supplemental Declaration Of Robert D. Tucker, Ph.D., M.D. Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
32. Supplemental Declaration Of John R. LaCourse, Ph.D., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
33. Direct Examination Of Robert D. Tucker, Ph.D., M.D., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction; filed September 3, 1998;
34. Direct Examination Of Robert A. Armitage, Esq., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
35. Direct Examination Of John R. LaCourse, Ph.D., Filed In Support Of Ethicon's Opposition To ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
36. ArthroCare's Supplemental Memorandum In Response To The Supplemental Declaration Of Robert A. Armitage, filed September 3, 1998;
37. Direct Testimony Of John T. Raffle In Support Of ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;
38. Direct Testimony Of Philip E. Eggers In Support Of ArthroCare's Motion For Preliminary Injunction, filed September 3, 1998;

39. Joint Statement Regarding Differences Between The Two Translations Of The Elsasser And Roos Article Proffered By Defendants, filed September 22, 1998;
40. Memorandum Decision And Order Regarding Preliminary Injunction Motion, issued December 2, 1998;
41. Ethicon's Response To ArthroCare's First Set Of Interrogatories To Defendant Ethicon, served November 6, 1998;
42. Plaintiff ArthroCare's Response To Defendant Gynecare, Inc.'s First Set Of Interrogatories, served November 10, 1998;
43. Plaintiff ArthroCare's Response To Mitek's First Set Of Interrogatories, served November 10, 1998;
44. Plaintiff ArthroCare's Response To Defendant Ethicon, Inc.'s First Set Of Interrogatories, served November 10, 1998;
45. Plaintiff ArthroCare's Objections And Responses To Defendants' First Set Of Requests For Admissions, served January 4, 1999;
46. Plaintiff ArthroCare's Objections And Responses To Defendant Gynecare, Inc.'s Second Set Of Interrogatories, served January 4, 1999;
47. Plaintiff ArthroCare's Supplemental Objections And Responses to Defendants' Request For Admission No. 36, served January 5, 1999;
48. Expert Witness Report Of John R. LaCourse, served January 8, 1999;
49. Expert Witness Report Of Robert D. Tucker, served January 8, 1999;
50. Expert Witness Report Of David J. Parins, served January 8, 1999;
51. Expert Witness Report Of Robert A. Armitage, Esq., served January 8, 1999;
52. Expert Witness Report Of Massoud Motamedi, Ph.D., served January 8, 1999;
53. Expert Witness Report Of Ashley J. Welch, Ph.D., served January 8, 1999;
54. Responsive Expert Report Of Leslie A. Geddes, Ph.D., served January 29, 1999;
55. Responsive Expert Report Of Donald W. Banner served January 29, 1999;
56. Supplemental Expert Report Of David J. Parins served February 9, 1999;
57. Ethicon's Motion For Summary Judgment Of Invalidity For Failure To Satisfy The Requirements Of 35 U.S.C. §§102-103, filed March 5, 1999;
58. Joint Statement Of Uncontested Facts In Support Of Ethicon's Motion For Partial Summary Judgment Of Invalidity Under 35 U.S.C. §§102 And 103, filed March 5, 1999;

59. Plaintiff ArthroCare's Opposition To Defendants' Motion For Summary Judgment Of Invalidity Under 35 U.S.C. §§102-103, filed March 18, 1999;
60. Ethicon's Reply Memorandum In Support Of Motion For Summary Judgment Of Invalidity Under 35 U.S.C. §§102 And 103, filed March 25, 1999;
61. Ethicon's Motion For Partial Summary Judgment Of Invalidity For Failure To Satisfy The Requirements Of 35 U.S.C. §112, filed March 5, 1999;
62. Joint Statement Of Uncontested Facts In Support Of Ethicon's Motion For Partial Summary Judgment For Invalidity For Failure To Satisfy The Requirements Of 35 U.S.C. §112, filed March 5, 1999;
63. Plaintiff ArthroCare's Opposition To Defendants' Motion For Partial Summary Judgment Of Invalidity For Failure To Satisfy The Requirements Of 35 U.S.C. §112, filed March 18, 1999;
64. Ethicon's Reply Memorandum In Support Of Motion For Partial Summary Judgment Of Invalidity For Failure To Satisfy The Requirements Of 35 U.S.C. §112, filed March 25, 1999;
65. Declaration Of Leslie A. Geddes, Ph.D., In Support Of ArthroCare's Oppositions To Defendants Motions For Partial Summary Judgment, filed March 18, 1999;
66. Plaintiff ArthroCare's Motion For Partial Summary Judgment That Claims Are Not Anticipated Or Rendered Obvious By Certain References, filed March 5, 1999;
67. Ethicon's Opposition To ArthroCare's Motion For Partial Summary Judgment That Claims Are Not Anticipated Or Rendered Obvious By Certain References, filed March 18, 1999;
68. ArthroCare's Reply Brief In Support Of ArthroCare's Motion For Partial Summary Judgment That Claims Are Not Anticipated Or Rendered Obvious By Certain References, filed March 25, 1999;
69. Plaintiff ArthroCare's Motion For Partial Summary Judgment Of No Inequitable Conduct Or, Alternatively, For Bifurcation, filed March 5, 1999;
70. Joint Statement Of Undisputed Facts In Support Of ArthroCare's Motion For Partial Summary Judgment Of No Inequitable Conduct Or, Alternatively, For Bifurcation, filed March 5, 1999;
71. Ethicon's Opposition Of Plaintiff ArthroCare's Motion For Partial Summary Judgment Of No Inequitable Conduct Or Alternatively For Bifurcation, filed March 18, 1999;
72. Declaration Of Robert A. Armitage, Esq., In Support Of Defendant Ethicon, Inc.'s Opposition To ArthroCare's Motion For Summary Judgment, filed March 18, 1999;
73. Plaintiff ArthroCare's Reply Brief In Support Of Its Motion For Partial Summary Judgment Of No Inequitable Conduct Or, Alternatively, For Bifurcation, filed March 25, 1999;

74. Plaintiff ArthroCare's Motion For Partial Summary Judgment That Defendants Cannot Prevail On Their Enablement And Written Description Defenses As To Certain Claims, filed March 5, 1999;
75. Joint Statement Of Undisputed Facts In Support Of ArthroCare's Motion For Partial Summary Judgment That Defendants Cannot Prevail Under Enablement And Written Description Defenses As To Certain Claims, filed March 5, 1999;
76. Ethicon's Opposition To ArthroCare's Motion For Partial Summary Judgment That Defendants Cannot Prevail On Their Enablement And Written Description Defenses As To Certain Claims, filed March 18, 1999;
77. ArthroCare's Reply Brief In Support Of ArthroCare's Motion For Partial Summary Judgment That Defendants Cannot Prevail On Their Enablement And Written Description Defenses As To Certain Claims, filed March 25, 1999;
78. Defendants' Trial Brief On The Issues Of Unenforceability And Invalidity Under 35 U.S.C. §§102, 103, And 112, filed March 29, 1999;
79. Plaintiff ArthroCare's Trial Brief Re: Validity And Enforceability Of The Patents-In-Suit, filed April 7, 1999;
80. Defendants' Notice Of Prior Art Pursuant To 35 U.S.C. §282, filed April 9, 1999;
81. April 26, 1999 Letter From Defendants To The Court Regarding Additional Claim Construction Issues;
82. Joint Proposed Jury Instructions For Claims 46, 55, 58, 59, 61, And 62 Of U.S. Patent No. 5,697,536;
83. April 30, 1999 Letter From ArthroCare To The Court Regarding Additional Claim Construction Issues;
84. Expedited Motion Of Plaintiff ArthroCare Corporation Regarding Joint Jury Instructions, filed May 13, 1999.

In addition to the above-listed materials, there are numerous other papers that were filed with the Court in connection with the *Ethicon* litigation, some of which were designated confidential pursuant to a protective order. Furthermore, depositions were taken of numerous witnesses regarding validity and enforceability issues, some of which are also confidential. If the Examiner desires, Applicant will submit any or all of the listed materials, other papers filed with the court, and/or transcripts of depositions to the Examiner for consideration, or, if necessary, will contact the parties who designated such material confidential and inquire into changing the designation of such material.

Applicant will also provide any additional information that the Examiner desires about the *Ethicon* litigation or the materials described herein.

B. *Smith & Nephew* litigation

On July 25, 2001, ArthroCare Corporation commenced an action in the United States District Court for the District of Delaware against Smith & Nephew, Inc. (“Smith & Nephew”) for infringement of U.S. Patent Nos. 5,697,536 (“the ‘536 Patent”), 5,697,882 (“the ‘882 Patent”) and 6,224,592 (“the ‘592 Patent”). That action was assigned Civil Action No. 01-504-SLR (the “*Smith & Nephew* litigation”). The *Smith & Nephew* litigation proceeded to trial commencing on April 30, 2003.

On May 12, 2003, the jury returned a verdict in favor of ArthroCare on infringement and validity issues with respect to all three patents. A copy of the jury’s verdict, dated May 12, 2003, is enclosed. Thereafter, on June 20, 2003, the Court entered judgment on the jury’s verdict. A copy of the judgment is enclosed.

Numerous papers were filed with the Court during the *Smith & Nephew* litigation. The official docket kept by the clerk of the Delaware District Court, which is 43 pages long, is enclosed. The files holding the documents corresponding to the docket entries on the official docket span approximately eight linear feet of shelving space. Applicant is enclosing herewith the following documents from the *Smith & Nephew* litigation which show Smith & Nephew’s and Applicant’s primary arguments relating to issues of validity and enforceability:

1. Smith & Nephew’s Supplemental Responses to Plaintiff ArthroCare’s Interrogatories Nos. 4 And 5, dated December 19, 2001;
2. Smith & Nephew’s Supplemental Invalidity And Infringement Contentions, served March 29, 2002<sup>1</sup>;
3. Smith & Nephew’s Supplemental Invalidity Contentions, served June 3, 2002;
4. Smith & Nephew’s Supplemental Invalidity Contentions, served September 10, 2002;
5. Smith & Nephew’s Supplemental Invalidity Contentions, served October 9, 2002;
6. ArthroCare’s Validity Contentions, served October 15, 2002;
7. Memorandum Order Re: Claim Construction, filed April 9, 2003;
8. Smith & Nephew’s Notice Pursuant To 35 U.S.C. § 282;

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1. Smith & Nephew marked its infringement contentions “Highly Confidential – Attorneys’ Eyes Only” under the protective order. Accordingly, Applicant has secured redacted pages that omit Smith & Nephew’s infringement contentions from this document.

9. Trial Testimony Of Smith & Nephew's Expert Dr. Kim Manwaring on May 6, 2003;
10. Trial Testimony Of Smith & Nephew's Expert Dr. Kenneth Taylor on May 7 & 8, 2003;
11. Jury Verdict, dated May 12, 2003;
12. Judgment In A Civil Case, filed June 20, 2003;
13. Smith & Nephew's Opening Brief In Support Of Its Inequitable Conduct Case, filed June 9, 2003;
14. Smith & Nephew's Opening Brief In Support Of Its Rule 50(b) Motion For Judgment As A Matter Of Law, filed June 30, 2003;
15. ArthroCare's Corrected Answering Brief In Opposition To Smith & Nephew's Opening Brief In Support Of Its Inequitable Conduct Case, filed July 11, 2003<sup>2</sup>;
16. ArthroCare's Answering Brief In Opposition To Smith & Nephew's Rule 50(b) Motion For Judgment As A Matter Of Law, filed July 30, 2003;
17. Smith & Nephew's Reply Brief In Support Of Its Rule 50(b) Motion For Judgment As A Matter Of Law, filed August 14, 2003.

In addition to the above documents, a number of post trial motions were filed on the issues of infringement, invalidity, and inequitable conduct. In particular, Smith & Nephew filed a motion for judgment as a matter of law; a motion for a new trial; a cross motion to strike ArthroCare's motion for entry of judgment of no inequitable conduct and a motion to modify the protective order. ArthroCare filed a motion for entry of judgment of no inequitable conduct and a motion for a permanent injunction.

On March 10, 2004 the Court ruled in favor of ArthroCare on all post trial motions. The Court issued a 90 page memorandum opinion: 1.) denying Smith & Nephew's motion for judgment as a matter of law; 2.) denying Smith & Nephew's motion for a new trial; 3.) granting ArthroCare's motion for entry of judgment of no inequitable conduct; 4.) denying Smith & Nephew's cross motion to strike ArthroCare's motion for entry of judgment of no inequitable conduct; 5.) granting ArthroCare's motion for a permanent injunction; and 6.) denying Smith & Nephew's motion to modify the protective order. The Court also issued, on March 10, 2004, a memorandum opinion granting ArthroCare's motion to dismiss Smith & Nephew's antitrust counterclaims.

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<sup>2</sup> Smith & Nephew's Reply Brief In Support Of Its Inequitable Conduct Case, dated July 24, 2003, was filed under seal by Smith & Nephew. If the Examiner requests a copy, Applicant will contact Smith & Nephew in an attempt to secure an agreement by which the brief can be disclosed.

On June 9, 2004, the Court issued an order enjoining Smith and Nephew from directly infringing, inducing the infringement, and contributing to the infringement of the '536 Patent, the '882 Patent and the '592 Patent. The above mentioned memorandum opinions and corresponding orders are enclosed for your consideration<sup>3</sup>.

In addition to the above-listed materials, there are numerous other papers that were filed with the Court or served in connection with the *Smith & Nephew* litigation that relate to invalidity or enforceability issues. These include, for example, the expert reports of Dr. S. Nahum Goldberg (ArthroCare's expert on infringement and validity), Dr. Kenneth Taylor (Smith & Nephew's expert on infringement and invalidity), Dr. Kim Manwaring (Smith & Nephew's expert on invalidity), Dr. Michael Choti (Smith & Nephew's expert on infringement and invalidity), Charles Van Horn (ArthroCare's expert on patent prosecution issues), and Ronald Panitch (Smith & Nephew's expert on patent prosecution issues). Smith & Nephew also served a paper purportedly prepared by Dr. Brian Skromme of Arizona State University related to the validity of the '882 patent. Moreover, the parties filed motions for summary judgment on issues pertaining to the validity of the patents-in-suit. The briefs in support of and opposition to these motions are listed as docket numbers 247, 248, 257, 258, 261, 262, 280, 283, 292, 298, 300, and 302 on the official docket that ArthroCare has enclosed. Smith & Nephew also produced a declaration from Eberhard Roos, the named inventor on U.S. Patent No. 4,116,198 and co-author of the Roos and Elsasser article ("Über ein Instrument zur leckstromfreien transurethralen Resektion"), both of which were references asserted in the Smith & Nephew litigation. There also are many trial exhibits. In addition, pre-trial depositions were taken of several witnesses regarding validity and enforceability issues, including depositions of Dr. Goldberg, Dr. Taylor, Dr. Manwaring, Dr. Choti, Mr. Van Horn, and Mr. Panitch. A list of the depositions taken in the *Smith & Nephew* litigation is set forth below:

1. John Tighe, taken September 18, 2002 and November 8, 2002 (ArthroCare employee, fact witness);
2. Diane DeLucia, taken September 19, 2002 (Smith & Nephew employee, fact witness);
3. John Raffle, taken September 19, 2002 and November 11, 2002 (ArthroCare employee and patent attorney, fact witness);
4. James Heslin, taken September 24, 2002 (patent attorney, fact witness);

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<sup>3</sup> A portion of the memorandum opinion discussing the antitrust issues has been redacted to preserve information that is confidential



5. Fernando Sanchez, taken September 24, 2002 (ArthroCare employee, fact witness);
6. Duane Marion, taken September 28, 2002 (former Smith & Nephew employee, fact witness);
7. John Graf, taken October 1, 2002 (Smith & Nephew employee, fact witness);
8. Hira Tahpliyal, taken October 1, 2003 and November 14, 2002 (co-inventor of patents-in-suit, fact witness);
9. Jim Pacek, taken October 3, 2002 and November 7, 2002 (ArthroCare employee, fact witness);
10. John Konsin, taken October 3, 2002 (Smith & Nephew employee, fact witness);
11. Jean Woloszko, taken October 3, 2002 (ArthroCare employee, fact witness);
12. Andrew Eggers, taken October 4, 2002 (employee of Eggers & Associates (owned by Philip E. Eggers, co-inventor of patents-in-suit), fact witness);
13. Bruce Prothro, taken October 4, 2002 (ArthroCare employee, fact witness);
14. Kara Weldon, taken October 5, 2002 (current or former Smith & Nephew employee, fact witness);
15. David Balford, taken October 5, 2002 (Smith & Nephew employee, fact witness);
16. Allen Weinstein, taken October 8, 2002 (ArthroCare employee, fact witness);
17. Christine Hanni, taken October 10, 2002 (former ArthroCare employee, fact witness);
18. Linda Guthrie, taken October 11, 2002 (Smith & Nephew employee, fact witness);
19. Michael Baker, taken October 11, 2002 (ArthroCare CEO, fact witness);
20. Kate Knudsen, taken October 11, 2002 and November 7, 2002 (Smith & Nephew employee, fact witness);
21. Sally Maher, taken October 11, 2002 (Smith & Nephew employee, fact witness);
22. Ron Sparks, taken October 11, 2002 (Smith & Nephew CEO, fact witness);
23. Philip E. Eggers, taken October 15 and 29, 2002, November 13, 2002, and April 30, 2003 (co-inventor of patents-in-suit, fact witness);
24. Tom Ross, taken October 15, 2002 (current or former employee of Oratec Interventions, Inc. (acquired by Smith & Nephew), fact witness);
25. Jack Cordes, taken October 15, 2002 (former employee of Eggers & Associates, fact witness);
26. Michael Long, taken October 29, 2002 (former Smith & Nephew employee, fact witness);
27. Joan McCreary, taken October 30, 2002 (Smith & Nephew employee, fact witness);
28. Todd Plevinsky, taken October 31, 2002 (former Smith & Nephew employee, fact witness);
29. Karen Drucker, taken November 1 and 14, 2002 (Smith & Nephew employee, fact witness);
30. Allen Gannon, taken November 1, 2002 (Smith & Nephew employee, fact witness);

31. Jim Pacek, taken November 7, 2002 (ArthroCare employee, fact witness);
32. Tim Crabtree, taken November 7, 2002 (former Smith & Nephew employee, fact witness);
33. John Konsin, taken November 7, 2002 (Smith & Nephew employee, fact witness);
34. Jason Krieser, taken November 13, 2003 (Smith & Nephew employee, fact witness);
35. Dr. Kim Manwaring, taken March 20, 2003 (Smith & Nephew expert witness);
36. Dr. Eliot Leitman, taken March 25, 2003 (ArthroCare expert witness);
37. Dr. Kenneth Taylor, taken March 27 and 28, 2003 (Smith & Nephew expert witness);
38. Dr. S. Nahum Goldberg, taken March 27 and 28, 2003 (ArthroCare expert witness);
39. Ronald Panitch, taken March 28, 2003 (Smith & Nephew expert witness);
40. Dr. Michael Choti, taken March 30, 2003 (Smith & Nephew expert witness);
41. Charles Van Horn, taken April 3, 2003 (ArthroCare expert witness);
42. Creighton Hoffman, taken April 4, 2003 (ArthroCare expert witness);
43. Brian Napper, taken April 17, 2003 (Smith & Nephew expert witness);
44. Warren Heim, taken April 22, 2003 (consultant to Smith & Nephew, fact witness).

Smith & Nephew designated many of the materials from the *Smith & Nephew* litigation as confidential pursuant to the protective order in that case. Without admitting the materiality or relevance of the foregoing materials, Applicant will submit any or all of the foregoing materials to the Examiner for consideration or, if the Examiner requests materials that have been filed under seal or designated confidential pursuant to the protective order, Applicant will contact Smith & Nephew in an attempt to secure an agreement by which such materials can be disclosed.

## II. REEXAMINATION

### A. The '536 Patent

On December 23, 1999, an *Ex Parte* Reexamination Request ("Request") for the '536 Patent was filed with the PTO. Applicant has enclosed a copy of the file history for the '536 Reexamination with this Information Disclosure Statement. The Request sought reexamination of claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60, and 63 of the '536 Patent in light of U.S. Patent 4,116,198 ("the Roos '198"). The PTO granted the Request on October 27, 2000.

On November 15, 2002, the PTO mailed an Office Action. The Office Action is divided into two sections. Section I sets forth the conclusion of the examiner and a board of primary

examiners that “the Roos ‘198 does not anticipate or render obvious any of the independent claims of record.” *See* November 15, 2002 Office Action at 3. Section II contains a rejection of claims 1-64 of the ‘536 Patent as anticipated under 35 U.S.C. § 102(b) and obvious under 35 U.S.C. § 103 in light of certain references identified in an Information Disclosure Statement filed by Applicant on June 19, 2002. On December 19, 2002, Applicant submitted a Response to the Office Action.

On March 14, 2003, the PTO issued a Notice of Intent to Issue *Ex Parte* Reexamination Certificate (“NIRC”). The NIRC states that “the examiner of record concurs with the arguments presented by patent Applicant on paper number 15. Accordingly, it is concluded that claims 1-64 are allowable over the prior art of record.” *See* NIRC at 2. A Reexamination Certificate issued on June 10, 2003.

Additionally, on April 9, 2003, another *Ex Parte* Reexamination Request for the ‘536 Patent was filed with the PTO. The Request sought reexamination of claims 1, 2, 5, 9, 14, 15, 25, 26, 28, 30-33, 36, 38, 40, 42-47, 49, 53, 55, 56, 58, 59, 61, and 63 of the ‘536 Patent in light of the Roos ‘198; Elasser and Roos, “Uber ein Instrument zur leckstromfreien transurethralen resection,” Medizinal-Markt/Acto Medicotechnica, Vol. 24, No. 4/1976, pp. 129-134 (“the Elasser and Roos article”); U.S. Patent Nos. 4,805,616; 4,674,499; 4,381,007; 5,217,459; and 5,007,908. The PTO granted the Request on June 30, 2003. It has been assigned Reexamination No. 90/006,597.

#### B. The ‘882 Patent

On April 18, 2003, an *Ex Parte* Reexamination Request for the ‘882 Patent was filed with the PTO. The Request sought reexamination of claims 1, 13, 17, 18, 24, 26, 28, 29, 48 and 54 of the ‘882 Patent in light of U.S. Patent Nos. 5,122,138; 5,007,908; and Slager et al., “Vaporization Of Atherosclerotic Plaques By Spark Erosion,” JACC Vol. 5, No. 6, June 1985:1382-6 (“the Slager Article”). The PTO granted the Request on July 1, 2003. It has been assigned Reexamination No. 90/006,607.

#### C. The ‘592 Patent

On April 21, 2003, an *Ex Parte* Reexamination Request for the ‘592 Patent was filed with the PTO. The Request sought reexamination of claims 1, 3, 4, 9, 11, 21, 23, 26, 27, 30, 32 and 42 of the ‘592 Patent in light of the Roos ‘198; the Elasser and Roos article; U.S. Pat. Nos. 4,381,007 to Doss;

and the Slager Article. The PTO granted the Request on July 7, 2003. It has been assigned Reexamination No. 90/006,611.

Should the Examiner desire copies of any of the documents filed in connection with the above reexaminations Applicant will submit them upon a request to do so in writing from the Examiner.

## III. CO-PENDING PATENT APPLICATIONS

The following is a list of co-pending applications:

Application No.	Filing Date
09/293,231	16-Apr-1999
09/314,247	18-May-1999
09/338,842	23-Jun-1999
09/347,390	06-Jul-1999
09/354,835	16-Jul-1999
09/360,075	23-Jul-1999
09/372,454	11-Aug-1999
09/457,201	06-Dec-1999
09/501,327	09-Feb-2000
09/512,742	24-Feb-2000
09/539,147	30-Mar-2000
09/562,496	01-May-2000
09/562,650	01-May-2000
09/586,295	02-Jun-2000
09/679,394	03-Oct-2000
09/709,035	08-Nov-2000
09/735,426	12-Dec-2000
09/747,311	20-Dec-2000
09/758,403	10-Jan-2001
09/771,299	25-Jan-2001
09/780,745	09-Feb-2001
09/791,504	22-Feb-2001
09/796,094	28-Feb-2001
09/839,427	20-Apr-2001
09/845,034	27-Apr-2001
09/848,843	03-May-2001
09/963,736	26-Sep-2001
10/057,412	25-Jan-2002
10/072,599	05-Feb-2002
10/082,017	20-Feb-2002
10/097,763	13-Mar-2002
10/135,478	30-Apr-2002
10/139,117	03-May-2002
10/174,266	18-Jun-2002
10/175,472	18-Jun-2002
10/175,555	18-Jun-2002
10/187,733	27-Jun-2002
10/264,308	02-Oct-2002
10/288,227	04-Nov-2002

Application No.	Filing Date
10/290,930	07-Nov-2002
10/291,213	08-Nov-2002
10/339,470	09-Jan-2003
10/367,608	13-Feb-2003
10/372,591	21-Feb-2003
10/374,411	25-Feb-2003
10/384,050	05-Mar-2003
10/389,159	13-Mar-2003
10/621,839	16-Jul-2003
10/437,260	13-May-2003
10/402,728	28-Mar-2003
10/392,529	20-Mar-2003
10/389,159	14-Mar-2003
10/613,609	02-Jul-2003
10/435,825	12-May-2003
10/613,115	03-Jul-2003
10/621,839	16-Jul-2003
10/661,118	12-Sep-2003
10/656,597	05-Sep-2003
10/682,600	09-Oct-2003
10/713,643	13-Nov-2003

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'RR Batt', with a stylized flourish at the end.

Richard R. Batt  
Reg. No. 43,485

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